

IN THE UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA,

Plaintiff,

v.

Case No. 23-CV-168-JFH-CDL

**250,000 FILLED BOTTLES OF
LIQUID PRODUCT, MORE OR
LESS, OF FINISHED PRODUCT,
CONTAINING KRATOM,
LABELED IN PART: “BOTANIC
TONICS FEEL FREE PLANT
BASED HERBAL
SUPPLEMENT,” ET AL.,**

Defendant Articles.

**CLAIMANT BOTANIC TONICS, LLC’S REPLY
BRIEF IN SUPPORT OF ITS MOTION TO
DISMISS FIRST AMENDED VERIFIED COMPLAINT**

The government’s brief in opposition improperly seeks to shift the burden to Claimant Botanic Tonics, includes extraneous facts that should be disregarded by the Court, and does not (and cannot) justify its fatal decision to forgo actual facts in favor of conclusory allegations in its complaint. Accordingly, the First Amended Complaint must be dismissed.

**THE GOVERNMENT IMPROPERLY ATTEMPTS TO SHIFT THE BURDEN OF
PROOF BECAUSE IT FAILED TO ADDRESS 21 U.S.C. § 350B IN ITS COMPLAINT.**

The government does not dispute that it has the “burden of proof on each element to show that a dietary supplement is adulterated.” 21 U.S.C. § 342(f). To state a claim that the Defendant Articles are adulterated and subject to seizure, the government must allege not only that they are adulterated under section 342(f)(1)(B), but it also must allege that section 350b(a) is inapplicable. That is because a dietary supplement containing a new dietary ingredient is not adulterated if the dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered. 21 U.S.C. §

350b(a)(1). The government’s sole allegation is that there is “inadequate information to provide reasonable assurance that this ingredient does not present a significant or unreasonable risk of illness or injury,” under 21 U.S.C. § 342(f)(1)(B). However, the alleged lack of information does not matter if the dietary ingredient has been present in the food supply. Accordingly, the government was required to allege that section 350b(a) has not been met, and it failed to do so.

Moreover, the government was certainly aware of 21 U.S.C. § 350b because it cited subsection 350b(d) in its complaint. (First Amended Complaint, Doc. 9 at ¶ 8). Yet the government does not reference section 350b(a)(1 or 2) in its complaint. Instead, the government argues in its brief that section 350b(a) only provides circumstances when a manufacturer may be required to comply with FDA’s New Dietary Ingredient notification process. (Gov’t Opp, Doc. 20 at p. 9). The government is wrong. Section 350b(a)(1) does not require pre-notification to FDA. By its express terms, 21 U.S.C. § 350b(a)(1) provides that a dietary supplement that contains a new dietary ingredient (as the government alleges about Botanic Tonics’s product) is not adulterated if it has been present in the food supply in a form in which the food has not been chemically altered.

The most logical reason for the government’s failure to address this essential statutory element required is because the government knows it cannot truthfully allege that kratom has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered. In fact, the government does not contest FDA’s statements in a prior case that kratom is a “food” and “used for food or drink for humans or used as a component of such food or drink.” *In re Admin. Establishment Inspection of Spa & Organic Essentials of Penn., LLC*, 2019 WL

1651607, at *1 - 2, and that kratom has been in the food supply for years and is legal in 44 states, including Oklahoma. (Motion to Dismiss, Doc. 12 at p. 9).¹

When confronted with this glaring omission from its complaint, the government tries to flip the burden and claim that section 350b places no requirements on the government but instead is only an affirmative defense. (Gov't Opp., Doc. 20, pp. 8-9). Thus, the government argues that it can seize property from a company with an ex parte order then audaciously claim that the company has the burden to prove that its property was improperly taken. Not surprisingly, the government is unable to cite a single case for its novel attempt to escape its own statutory burden. The law is clear that it is the government's burden to properly allege (and prove) that the seized products are adulterated. Its failure to address section 350b in its complaint renders the complaint defective and subject to dismissal.

THE COURT SHOULD DISREGARD THE GOVERNMENT'S ATTEMPT TO DEFEND ITS COMPLAINT BY REFERENCING EXTRANEOUS ALLEGATIONS.

The government's decision to include more than a page of new, unverified factual allegations that were not in its amended complaint is a tacit admission that the amended complaint is insufficient to state a claim. (Gov't Opp., Doc 20 at pp. 2-3). As explained in Botanic Tonics's motion and below, conclusory allegations are to be disregarded when assessing the sufficiency of a complaint. Botanic Tonics noted in its motion to dismiss that the complaint contained only unsupported, conclusory allegations that kratom "can" have negative health impacts, and specifically called out the government for failing to cite a single study, adverse event, or any non-conclusory fact in its complaint.

¹ Unlike the government's use of "facts" outside the four corners of its complaint such as FDA's own press releases, this information is based on a federal case and state statutes.

In response to the motion to dismiss, the government improperly includes “facts” outside the complaint. The government cites to FDA press releases and a 2017 statement from a former FDA commissioner, claiming that there have been adverse events associated with kratom. The former commissioner’s statement, for example, mentioned that complaints about kratom have increased, and that “there are no FDA-approved therapeutic uses of kratom.” (Gov’t Opp., Doc. 20 at p. 3). None of these claims, or any other information in the press releases, are in the amended complaint. The government is essentially just citing its own press statements in an attempt to bolster its insufficient complaint.

The government’s reference to extraneous evidence outside the factual allegations in its verified amended complaint is improper, and the Court should not consider such information. A plaintiff may not amend its complaint through its brief in opposition to the defendant’s motion to dismiss.² *Thomason v. Nachtrieb*, 888 F.2d 1202, 1205 (7th Cir. 1989); *Car Carriers, Inc. v. Ford Motor Company*, 745 F.2d 1101, 1107 (7th Cir. 1984) (“[I]t is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss.”). And, in ruling on a motion to dismiss for failure to state a claim, a court should not consider material beyond the pleadings unless submitted or attached to the complaint. *Car Carriers, Inc.*, 745 F.2d at 1107 (“Similarly, consideration of a motion to dismiss is limited to the pleadings.”); *Nichols v. United States*, 796 F.2d 361, 366 (10th Cir. 1986) (“Our review must be limited to whether it appears from the

² To the extent the government seeks leave to amend its First Amended Complaint to include some or all of these extrinsic allegations, Botanic Tonics objects because such “facts” were fully known by the government at the time of its original complaint. Moreover, including them would be futile because it would not cure the deficiencies of the complaint. *Full Life Hospice, LLC v. Sebelius*, 709 F.3d 1012, 1018 (10th Cir. 2013) (“[A] district court may refuse to allow amendment if it would be futile.... A proposed amendment is futile if the complaint, as amended, would be subject to dismissal.”) (internal citations omitted); *Jefferson Cnty. Sch. Dist. No. R-1 v. Moody's Investor's Servs., Inc.*, 175 F.3d 848, 859 (10th Cir. 1999).

pleadings that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.”).

Although some material “submitted as an exhibit to a pleading or incorporated or referenced in a complaint,” may be considered in adjudicating a Rule 12(b)(6) motion, *Johnson v. Figueroa*, No. CIV-12-1056-R, 2014 WL 2112662, at *2 (W.D. Okla. May 20, 2014) (citing *Tal v. Hagan*, 453 F.3d 1244 (10th Cir. 2006)), the government did not attach to or reference any of the FDA’s press releases or other documents in its complaint. Therefore, such statements should not be considered by the Court.

Under Federal Rule of Civil Procedure 12(d), if information outside the pleadings is presented to and not excluded by the Court, the motion can be treated as one for summary judgment. Fed. R. Civ. P. 12(d). However, it would be manifestly unjust for the government, having realized its complaint is flawed, to attempt to convert Botanic Tonics’s motion to dismiss into one for summary judgment by asking the Court to consider material beyond the complaint.

Moreover, the government has not requested that the Court take judicial notice of the FDA press releases and other extraneous information, and it would be improper to do so. Pursuant to Federal Rule of Evidence 201(b), “[t]he court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known within the trial court’s territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.” “[O]ne of the requirements for judicial notice is that the evidence in question is ‘not subject to reasonable dispute.’” *Herrick v. Garvey*, 298 F.3d 1184, 1192, n.5 (10th Cir. 2002); *see also MusclePharm Corp. v. Liberty Ins. Underwriters, Inc.*, 712 F. App’x 745, 757 (10th Cir. 2017) (“[J]udicial notice] is appropriate where a matter is ‘verifiable with certainty,’” such as “to

establish ‘adjudicative fact[s]’ that are generally known or ‘capable of accurate and ready determination’ by resort to reliable sources.” (citing *York v. Am. Tel. & Tel. Co.*, 95 F.3d at 948, 958 (10th Cir. 1996)). A speech by a former FDA commissioner or a press release by FDA is not a proper “fact” for judicial notice and is nothing more than hearsay. If litigation continues in this case (and Botanic Tonics respectfully submits it should not), the government’s “facts” and opinions on kratom will be hotly contested.³

Thus, the Court should simply disregard all of the purported “facts” in the government’s brief that were not in the First Amended Complaint.

THE GOVERNMENT’S BOILERPLATE AND CONCLUSORY ALLEGATIONS DO NOT MEET THE HEIGHTENED PLEADING STANDARD REQUIRED IN *IN REM* FORFEITURE COMPLAINTS.

The government mischaracterizes Botanic Tonics’s argument that the complaint should be dismissed for “lack of evidence.” (Gov’t Opp. Doc. 20 at p. 9). Botanic Tonics is not making any such argument. The complaint must be dismissed for lack of sufficient “factual allegations,” not lack of “evidence.” The government’s factual allegations about kratom are virtually non-existent. As drafted, the government’s First Amended Complaint simply concludes that kratom can be bad, and therefore, Botanic Tonics’s products must be adulterated. That is insufficient to

³ While not relevant to its motion and Botanic Tonics does not request it be considered by the Court in assessing the motion to dismiss, the government’s effort to smear Botanic Tonics’s business by discussing “facts” outside the complaint should not go unanswered. FDA claims that adverse event reports regarding kratom have increased, but FDA is fully aware that the number of adverse event reports related to kratom was fewer in 2022 than in 2018 and is almost identical to the number of adverse event reports related to caffeine intake. FDA Adverse Events Reporting System (FAERS) Public Dashboard (<https://fis.fda.gov/sense/app/95239e26-e0be-42d9-a960-9a5f7f1c25ee/sheet/7a47a261-d58b-4203-a8aa-6d3021737452/state/analysis>) (last visited June 21, 2023) (at webpage, run searches for “caffeine” and “herbals/mitragynine” using search icon on top left of webpage; 2022 count shows 221 cases for caffeine and 209 cases for herbals/mitragynine).

state a claim, and the government knows it. Presumably, that's why it improperly attempted to add factual allegations in its response brief.

The government is aware that there is a heightened pleading standard in civil seizure cases and that the Supreme Court pronouncements in *Twombly* and *Iqbal* provide guidance in assessing motions to dismiss in such cases. (Gov't Opp., Doc. 20 at p. 5). This is not simply an arcane legal requirement; it is both logical and acts as a backstop against potential government overreach. The pleading standard "is designed to guard against the improper use of seizure proceedings and to protect property owners against the threat of seizure upon conclusory allegations." *United States v. One Gulfstream G-V Jet Aircraft*, 941 F. Supp. 2d 1, 14 (D.D.C. 2013). Otherwise, the government can essentially shut down a business selling a product that is legal in Oklahoma and 43 other states with a barebones, conclusory complaint signed by a government employee who provides no foundational facts for his knowledge to support the claims.⁴

There is no dispute that conclusory allegations should not be considered by the Court. *Ashcroft v. Iqbal*, 566 U.S. 662, 678 (2009); *U.S. v. \$134,972.34 Seized from FNB Bank, Account No.-5351*, 94 F. Supp. 3d 1224, 1230 (N.D. Ala. 2015) ("[T]he court should determine the sufficiency of the complaint by first separating the factual and conclusory allegations, and then applying the standard of Supplemental Rule G(2)(f)."). Further, a complaint must allege enough facts to plausibly state a claim for which relief can be based. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570

⁴ Kratom, like any food or dietary supplement, has a limited shelf life. Botanic Tonics is concerned that the government can essentially seize its product and litigate until the shelf life is expired, thereby achieving its goal of removing the product from the marketplace without a judicial determination or trial verdict on whether its seizure was proper. Or, Botanic Tonics may obtain a pyrrhic victory, winning its case but not in time to distribute and sell its product. Viewed in this light, the government's decision to rush in and seek seizure on an "emergency" basis six months after inspecting Botanic Tonics's facility may implicate an unconstitutional taking without due process.

(2007) (requiring enough facts to “nudge” the claim “across the line from conceivable to plausible” in order to survive a motion to dismiss); *see also United States v. 17 Bank Accounts Containing Various Amounts of United States Currency*, No. 18-cv-189, 2019 WL 13225955 at *2 (March 29, 2019 D. Wyo.) (citing *Iqbal* that “[p]lausibility lies somewhere between possibility and probability.”). And Supplemental Rule G(2)(f) requires that the complaint “state sufficiently detailed facts to support a reasonable belief that the government will be able to meet its burden of proof at trial.” Fed. R. Civ. P. Supp. R. G(2)(f).

Paragraphs 12 – 14 of the First Amended Complaint allege that kratom could be harmful. These allegations are either conclusory statements or ones that do not nudge the claim across the line from conceivable to plausible. At its core, the government concludes that kratom could be harmful and then says that Botanic Tonics’s products contain some unknown amount of kratom. Therefore, the government claims the products are adulterated. Such reliance on conclusory statements and logistic leaps should not be countenanced by the Court and do not state “sufficiently detailed facts” as required by Supplemental Rule G(2)(f). Stating that kratom “can” lead to negative health impacts, or “can” be followed by withdrawal symptoms, merely alleges that hypothetical health problems from taking kratom in general are conceivable, not plausible. (FAC, ¶¶ 12, 14). After removing these conclusory statements, there is nothing left to support the government’s claim that there is inadequate information to provide a reasonable assurance that kratom does not present a significant or unreasonable risk of illness or injury.

The two cases and press release cited by the government that FDA “has conducted numerous *in rem* seizures of kratom and kratom-containing products” do not support its position that the present complaint is sufficient to state a claim. (Gov’t Opp., Doc. 20 at pp. 3 n. 7 and 10.)

First, the press release should not even be considered by the Court for the reasons set forth above. Second, the two cited cases are readily distinguishable. One of the cases, *United States v. 101 Cases, More or Less, Containing Bottles & Pouches of Articles of Drug Labeled in Part as Kratom Therapy*, was not litigated at all as the court granted the government's motion for a default judgment. No. CV-16-05138, 2016 WL 11002541 (C.D. Cal. Dec. 21, 2016). Thus, it provides no support for the government.

The other case relied on by the government, *United States v. 286,161 bottles, 209 dietary supplement cookie packs, and 45,521 packs, boxes, or granules, et al.*, actually supports Botanic Tonics's position because in that case the complaint was far more factually detailed than what the government filed here. No. 19-C-3876, 2020 WL 550598 (N.D. Ill. Feb 3, 2020). That case dealt with alleged violations of Good Manufacturing Practices, which are not alleged here. There, the government alleged a violation of 21 U.S.C. § 342(g)(1), which states that dietary supplements are adulterated if they have been "prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations". The government specifically alleged 17 GMP violations, and the complaint also specifically referenced an FDA form 483 that was provided to the claimant following an inspection, "outlining 27 'objectionable conditions' and giving specific examples of the inspectors' observations." *Id.* at *2. Such specific and detailed information was sufficient to support a reasonable belief that the government would be able to prove the property was adulterated and subject to forfeiture.⁵ *Id.* at *4. Conversely, the government does not allege

⁵ There was no reference to 21 U.S.C. § 350b(a) in the *United States v. 286,161 bottles* case, but the government did not have to address that statute in that case in order to state a claim. There, if the product was made in violation of GMP, then it would still be adulterated even if it was historically present in the food supply as an article used for food in a form in which the food has not been chemically altered.

here a specific, identifiable, and objective GMP violation.⁶ Instead, it alleges the Feel Free product is adulterated because, according to the subjective view of FDA, there is inadequate information to provide reasonable assurance that this ingredient does not present a significant or unreasonable risk of illness or injury. And in support of its viewpoint, the government provides the Court with only generic, conclusory and boilerplate statements that consumption of kratom “can” lead to negative health impacts. The government’s allegations are so generic, it may as well have been describing sugar, coffee, or alcohol. Its allegations are patently insufficient to state a claim, and the First Amended Complaint should be dismissed.

CONCLUSION

The executive branch’s power to seize its citizen’s private property is great indeed. It should be undertaken only when necessary and only in accordance with the law. The government’s complaint in support of its seizure of Botanic Tonics’s property is deficient because it does not cite one of the laws applicable to determining whether a product is adulterated and provides only conclusory allegations in support of its position. When made aware of these deficiencies, the government’s response was to request that the Court consider facts outside of what is actually alleged in the complaint. The Court should not condone the government’s overreach of its power by allowing it to retain Botanic Tonics’s property based on a deficient complaint that alleges only that kratom can be harmful. Thus, Botanic Tonics respectfully requests that the Court dismiss the First Amended Complaint.

⁶ The government alleges it conducted inspections of Botanic Tonics’s facility in October 2022, November 2022, and April 2023, but has never alleged a single GMP violation. (FAC, ¶¶ 9, 11).

DATED: 21 June 2023

Respectfully submitted,

s/ John D. Russell

John D. Russell, OBA No. 13343
GABLEGOTWALS
110 N. Elgin Ave., Ste. 200
Tulsa, Oklahoma 74120-1495
(918) 595-4800
jrussell@gablelaw.com

-and-

Aaron M. Danzig, *pro hac vice pending*
ARNALL GOLDEN GREGORY, LLP
171 17th St. NW, Suite 2100
Atlanta, GA 30363
(404) 873-8500
aaron.danzig@agg.com

Robert Durkin, *pro hac vice pending*
Kevin M. Bell, *pro hac vice pending*
ARNALL GOLDEN GREGORY, LLP
2100 Pennsylvania Ave. NW, Suite 350S
Washington, DC 20037
(202) 677-4030
robert.durkin@agg.com
kevin.bell@agg.com

COUNSEL FOR CLAIMANT
BOTANIC TONICS, LLC

CERTIFICATE OF SERVICE

I hereby certify that on 21 June 2023 I caused to be filed the above and foregoing pleading with the Clerk of Court via the Court's ECF system, which served a true copy on all counsel of record via the ECF system.

s/ John D. Russell

John D. Russell